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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,667	10/06/2003	Bret A. Ferree	BAF-15102/29	4076
25006	7590	08/21/2006	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C PO BOX 7021 TROY, MI 48007-7021			REIMERS, ANNETTE R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/679,667

Applicant(s)

FERREE, BRET A.

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

Upon further consideration, the last office action, i.e., final office action dated December 27, 2005, has been vacated. A new action follows.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, lines 4-5, "an element that allows movement between the lower and upper components along only two separate, independent axes" has not been disclosed in the specification. The specification only discloses a multiaxial ADR. As there is no distinction in the specification between movement along multiple axes and movement along only two separate, independent axes, the phrase "an element that allows movement between the lower and upper components along only two separate, independent axes" is considered new matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hedman et al. (U.S. Patent Number 4,759,769).

Hedman et al. disclose various embodiments of a multiaxial artificial disc replacement comprising a lower component, 28, adapted for fixation to an inferior vertebral body, at 64, an upper component, 26, adapted for fixation to a superior vertebral body, at 46, an element, 72 and 74, that allows movement between the lower and upper components along only two separate, independent orthogonal axes, and wherein one of the axes is generally medial-lateral and the other axis is generally anterior-posterior (see figures 1, 2, 6 and 7 and column 4, lines 22-64, and column 5, lines 34-35).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hedman et al. (U.S. Patent Number 4,759,769) in view of Mehdizadeh (U.S. Patent Number 6,231,609), cited by examiner on 892, paper number 20041207.

Hedman et al. disclose the claimed invention except for the element being a cruciate-shaped axle. Mehdizadeh discloses a multiaxial artificial disc replacement comprising a lower component, 12, an upper component, 11, and an element, 19, between the components (see figure 2). Mehdizadeh further shows that the element can be a coil spring or a cruciate-shaped spring (see figures 2, 9 and 10) and teaches that these are functionally equivalent structures. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Hedman et al. with the element being a cruciate-shaped spring instead of a coil spring, in view of Mehdizadeh, as such would merely constitute a substitution of functionally equivalent structures.

### **Response to Arguments**

Applicant's arguments filed on June 07, 2006, regarding the 35 U.S.C. § 112, first paragraph rejection have been fully considered, but they are not persuasive. Examiner respectfully disagrees with applicant that every figure of the specification shows "an element that allows movement between the lower and upper components along only two separate, independent axes." For example, in figure 4, the arrows indicate that the cruciate-shaped axes can allow for more than anterior-posterior and medial-lateral movement, e.g. rotational movement about a vertical axis.

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Applicant's arguments regarding claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EDUARDO O. ROBERT  
SUPERVISORY PATENT EXAMINER